

REMARKS

The January 18, 2007 Official Action has been carefully considered. In view of the amendment submitted herewith and these remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, it is noted that a shortened statutory response period of three (3) months was set in the January 18, 2007 Official Action. The initial due date for response, therefore, was April 18, 2007. A petition for a two (2) month extension of the response period is presented with this amendment and Request for Reconsideration, which is being filed before the expiration of the two (2) month extension period.

It is noted preliminarily, that as a result of applicants' election in response to the earlier restriction requirement, claims 51 and 63-68 have been examined on their merits. Among the claims that have been examined, claims 67 and 68 are free of the prior art, as noted at page 2 of the January 18, 2007 Official Action.

Claims 52-62 have been withdrawn from consideration in this application as drawn to non-elected subject matter. Applicants wish to make clear that their election in response to the aforementioned restriction requirement is without prejudice to their right to file one or more divisional applications, as provided in 35 USC §121, directed to the subject matter of withdrawn claims 52-62.

The January 18, 2007 Official Action includes an objection to the specification because the character "N" in "N- and C-termini" is missing from a number of passages in the specification. These informalities have been eliminated by the present amendment.

Turning to the substantive aspects of the January 18, 2007 Official Action, claim 52 stands rejected under 35 USC §112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention. Specifically, the expressions "proximity-sensor" and "at a distance which is" are deemed unclear by the examiner based on the dictionary definition of the terms "proximity" and "distance".

Claims 51 and 63-68 have been rejected for allegedly failing to comply with the written description requirement of 35 USC §112. According to the examiner, the specification fails to provide a written description of the genus of the claimed composition and does not reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the entire scope of the claimed invention.

Claims 51 and 63-66 have been further rejection under 35 USC §102(b) as allegedly anticipated by U.S. Patent 6,291,201 to Garman. Claims 51, 63, 64 and 66 have also been rejected under 35 USC §102(b) as allegedly anticipated by Gulnik et al., FEBS Letters (1997) and Jones et al., Anal. Biochem. (1997).

Claims 51, 63 and 64 have been rejected under 35 USC §103(a) as allegedly unpatentable over Gulnik et al., *supra*, in view of Garman, *supra*, and further in view of Lakowicz, Principles of Fluorescence Spectroscopy, 2nd ed. (1999).

The foregoing objection and rejections constitute all of the grounds set forth in the January 18, 2007 Official Action for refusing the present application.

In accordance with the present amendment, the specification has been amended at pages 11, 22, 27, 31, 35-37 and 46-47 to take care of the above-noted informalities concerning the N- and C-termini of the peptide substrates described in the present specification.

As for the claims, claim 51 has been amended by specifying that the utility of the claimed composition is for detecting the effect of a kinase on a peptide substrate, the kinase being effective to convert a site on the peptide substrate from an unphosphorylated to a phosphorylated state. Accordingly, the previous references to "unmodified state" and "modified state" in claim 51 have been deleted. Support for this aspect of the amendment is provided at page 23, lines 18-20 of the present specification. As now amended, claim 51 also calls for a substrate selected from the group of transcription factors, signal transduction factors or fragments thereof. Support for this aspect of the amendment is provided at page 23, lines 12, 13 and 19-21 of the present specification. The recitation in claim 51 to the effect that conversion of the peptide substrate site from the unphosphorylated (unmodified) state to the phosphorylated (modified) state occurs without cleavage of the peptide substrate has been moved from the preamble to the body of the claim. The new recitation in claim 51 that the first and second proximity sensors are spaced apart from one another find support in Figure 1 and the related text in the specification. A number of additional conforming amendments have been made in claim 51 which are in keeping with the above-noted changes.

Claim 64 has been amended to correct certain apparent typographical errors.

New claims 69-73 are also presented with this amendment. New claim 69 is analogous to claim 51, but is directed to a composition for detecting the effect of a phosphatase on a peptide substrate having the specified characteristics, rather than a kinase. New claims 70-73 correspond substantially to existing claims 63-66.

No new matter has been introduced into this application by reason of the amendment present herewith, entry of which is respectfully requested.

For the reasons set forth below, applicants respectfully submit that the 35 USC §112, first and second paragraph rejections of claims 51 and 63-68, as the case may be, and the prior art rejections of claims 51 and 63-66, as set forth in the January 18, 2007 Official Action, either lack merit or cannot be maintained in view of the present amendment or both. These grounds of rejection are, therefore, respectfully traversed.

**A. Claim 51 Fully Complies with the Definiteness Requirement of
35 USC §112, Second Paragraph**

The relevant inquiry in determining compliance with the definiteness requirement of 35 USC §112, second paragraph, is whether the claim in question sets out and circumscribes a particular area with a sufficient degree of precision and particularity, such that the metes and bounds of the claimed invention are reasonably clear. *In re Moore*, 169 USPQ 236 (CCPA 1971).

The definiteness of claim language may not be analyzed in the abstract, but must be considered in light of the supporting specification, with the language in question being accorded the broadest reasonable interpretation consistent with its ordinary usage in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicants' specification. *In re Morris*, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). See also *Ex parte Cole*, 223 USPQ 94 (Bd. Apps. 1983) (claims are addressed to the person of average skill in a particular art; compliance with §112 must be adjudged from that perspective, not in a vacuum).

Furthermore, it has long been held that the initial burden of establishing a failure to comply with 35 USC §112, second paragraph, rests upon the examiner. In rejecting a claim for alleged indefiniteness, therefore, it is incumbent upon the examiner to establish that one having ordinary skill in the art would not have been able to ascertain the scope of protection defined by the claim when read in light of the supporting specification. *Ex parte Cordova*, 10 USPQ2d 1949, 1952 (PTO BPAI 1988).

When the appropriate procedural approach is followed in assessing the claim terminology at issue, in accordance with the above-noted authorities, it is beyond question that applicant has satisfied the definiteness requirement of §112, second paragraph, with respect to the subject matter of claim 51.

The phrase “at a distance” has been deleted from claim 51, as now amended. Consequently, any indefiniteness that may have been engendered by the recitation of this phrase in the previous rendition to claim 51 has now been eliminated.

Considering the “enlightenment . . . that may be afforded by the written description contained in the applicant’s specification”, as per *In re Morris, supra*, the challenged recitation “proximity sensor peptide” cannot reasonably be considered unclear or indefinite. Applicant’s position in this regard is supported by the disclosure at page 18, lines 23-25 of the present specification, where it is expressly stated that “[a] proximity-sensor peptide refers to a peptide comprising a moiety capable of reporting its proximity on interacting with another peptide comprising a moiety, the moieties being, for example, a FRET pair”. In view of this disclosure, it is quite clear that the claim term “proximity sensor peptide” refers to a moiety that senses the nearness in place or relation of the first and second detectable proximity sensor peptides called for in claim 1. Thus, notwithstanding that the term “proximity” may also mean nearness in time, order or occurrence, one of ordinary skill in the art would not attribute these latter meanings to the term “detectable proximity sensor peptide”, as recited in applicant’s claims, as it would be unreasonable to do so in view of the above-quoted passage from the specification.

In summary, applicants’ position with respect to the 35 USC §112, second paragraph, rejection is that any person of ordinary skill in the art, having applicants’ disclosure and claims before him or her, would be apprised to a reasonable degree of certainty as to the exact subject matter encompassed within claim 51. Nothing more is required under 35 USC §112, second paragraph.

For all of the foregoing reasons, it is clear that in the present case, the examiner has failed to satisfy his burden of proof with respect to the §112, second paragraph, rejection of claim 51, as set forth in the February 27, 2007 Official Action. Accordingly, this ground of rejection is improper and should be withdrawn.

B. Applicant’s Specification Complies with the Written Description Requirement of 35 USC §112, First Paragraph, With Respect to Claims 51 and 63-68, as Now Amended

The relevant inquiry in determining compliance with the written description requirement of 35 USC §112, first paragraph, is whether the specification reasonably conveys to a person having ordinary skill in the relevant art that applicant, at the time the application

was filed, had possession of the claims invention. *In re Kaslow*, 217 USPQ 1089 (Fed. Cir. 1983).

Furthermore, the examiner has the initial burden of presenting evidence or reasons why a person of ordinary skill in the art would not recognize in the applicant's specification disclosure a description of the invention defined by the claims. *Ex parte Sorenson*, 3 USPQ2d 1462 (Bd. Pat. Apps. 1987).

As previously noted, the claims, as presently amended, are drawn to compositions comprising a functional peptide substrate for a kinase (claim 51) or a phosphatase (claim 69) which is converted from an unphosphorylated state to a phosphorylated state and vice versa. The January 18, 2007 Official Action indicates, at page 7, that this aspect of the present invention is adequately described. Indeed, the specification provides a working example describing the utility of the claimed composition for determining the effect of a kinase on a semi-synthetic peptide substrate having first and second detectable proximity sensors.

Moreover, it cannot reasonably be disputed that any number of semi-synthetic peptide substrates having multiple detectable proximity sensors incorporated therein, as required in claims 51 and 63-66, could be constructed by those skilled in the art on the basis of the detailed description provided in applicants' specification and knowledge available in the art. Under these circumstances, the examiner's rejection based on inadequate written description is untenable. As recently stated by the Federal Circuit in *Falkner v. Inglis*, 79 USPQ2d 1001 (Fed. Cir. 2006), none of the court's precedent pertaining to the written description requirement of 35 USC §112 requires a description, either by way of recitation or incorporation by reference, of that which was already known, citing *Capon v. Esshar*, 76 USPQ2d 1078 (Fed. Cir. 2005).

For the foregoing reasons, it is clear in the present case that the examiner has failed to satisfy her burden of proof as to the alleged inadequacy of the written description of applicant's invention, in relation to the composition for detecting the effect of a kinase on a peptide substrate having the particular characteristics required in claims 51 and 63-68. Accordingly, this ground of rejection should be withdrawn upon reconsideration.

**C. The Disclosures of Garman, Gulnik et al. and Jones et al. Fail to
Anticipate Claims 51 and 63-66, as Now Amended**

Rejections under 35 USC §102 are proper only when the claimed subject matter is

identically disclosed or described in the reference cited as evidence of anticipation. *In re Arkley*, 172 USPQ 524 (CCPA 1972). Applying this rule of law to the present case, the various 35 USC §102(b) rejections of claims 51 and 63-66, based variously on Garman, Gulnik et al. and Jones et al. are improper because the subject matter of the rejected claims is nowhere identically disclosed or described in the cited references.

None of the references cited in support of the §102(b) rejections discloses a semi-synthetic multiply labeled polypeptide substrate having a first structural confirmation when a site in the substrate is unphosphorylated, and a second structural confirmation when the same site is phosphorylated, as recited in claim 51. Moreover, none of the references cited as evidence of anticipation disclose the aspect of converting a site in a polypeptide substrate from an unphosphorylated state to a phosphorylated state without cleaving the backbone of the substrate, as called for in claim 51.

Inasmuch as neither Garman nor Gulnik et al. nor Jones et al. identically discloses or describes all of the claim recitations of applicant's claims 51 and 63-66, the §102(b) rejection of claims 51 and 63-66, as the case may be, based on those three (3) references is improper and should be withdrawn upon reconsideration.

**D. The Combined Disclosures of Gulnik et al., Garman and Lakowicz
do not Render Obvious the Subject Matter of Applicant's Claims
51, 63 and 64**

Concerning the rejection of claims 51, 63 and 64 based on Gulnik et al. in view of Garman and further in view of Lakowicz, the examiner's position in this regard is untenable for at least the same reasons previously discussed with respect to the impropriety of the §102 rejections of claims 51 and 63-66 based on Gulnik et al. and Lakowicz. In that Lakowicz does not compensate for the fundamental deficiencies noted above in the disclosures of Gulnik et al. and Garman, the §103 rejection of claims 51, 63 and 64 based on the combined disclosures of Gulnik et al., Garman and Lakowicz is likewise improper and should also be withdrawn upon reconsideration.

Finally, the examiner is correct in presuming at page 11 of the January 18, 2007 Official Action, that the subject matter of the various pending claims was commonly owned at the time the inventions covered therein were made.

In view of the present amendment and the foregoing remarks, it is respectfully urged that the objection and rejections set forth in the January 18, 2007 Official Action be withdrawn and that this application be passed to issue, and such action is earnestly solicited.

Respectfully submitted,

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